



May 29, 2018

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Secretary Alex M. Azar II  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Azar,

On behalf of the Board of Directors of Home Dialyzors United (HDU), I want to thank you for the opportunity to meet with you last Wednesday, May 16, 2018, in conjunction with ASN, AAKP and the KidneyX initiative. Your personal commitment and support for kidney issues is deeply appreciated and welcome. Nichole Jefferson and I truly appreciated the opportunity to discuss our personal journeys, as well as representing the voice of all home dialyzors.

HDU, a 501(c)(3) non-profit organization, is the only dialysis patient group dedicated to promoting home dialysis. Our mission is to inspire, inform, and advocate for an extraordinary quality of life for the home dialyzer community. We know from personal experience that, with the right dialysis treatment, many patients with ESRD (and their families and care partners) can lead a normal life, enjoying family and friends, and pursuing employment, education, volunteer, and leisure activities. HDU represents the patient voice of thousands of home dialyzors.

Since our time together was brief, we wanted to follow up with a personal letter of thanks and to bring to your attention another issue that presents a potentially debilitating effect on dialyzors in general, and particularly home dialyzors. Last year the MAC's introduced draft Local Coverage Determination (LCD) on frequency of hemodialysis, limiting all dialysis treatments to no more than three times per week. As we understand the proposed policy, it essentially says that payment for more frequent dialysis will be limited to temporary conditions, and cannot be used over the long term. As a result, it is possible that patients may not have access to the treatment their nephrologist has ordered to meet their medical needs. HDU represents the many thousands of home dialyzors who will ultimately be affected by these proposed changes. Denying dialysis patients access to the clinical benefits of more frequent hemodialysis could be potentially life-threatening at worst, and debilitating at best.

## Impact on Removing Barriers to Home Dialysis

HDU works diligently to encourage and expand the use of home dialysis. The home setting is the only practical location for the prescription of more frequent hemodialysis. In-center clinics are designed and optimized to provision three times per week dialysis, and alternative schedules are disruptive and not sustainable in the institutional dialysis setting. Given the clinical, patient, and economic benefits of contemporary home HD, it is difficult to understand why the proportions of home patients among high-income countries where home HD training and infrastructure are available remain so low. While peritoneal dialysis has always been the home therapy of choice, there are many patients who are unable to utilize this treatment modality. Therefore, one of the advantages of home hemodialysis is that patients who receive more frequent hemodialysis have improved clinical outcomes, not least of which are survival rates with nocturnal home HD being comparable to rates observed in deceased donor kidney transplant recipients.<sup>1</sup>

Home dialyzers are more likely to continue to work or return to work, thus remaining productive, tax paying citizens. With improved clinical outcomes achieved, patients who dialyze more frequently have the medical stability, mental clarity and energy to maintain independence and to seek employment. Home dialysis also allows the dialyzer to schedule their treatments around their work, instead of work around their dialysis, leading to more gainful employment opportunities. We strongly believe that the draft LCD creates a significant disincentive to the prescribing of home hemodialysis, by limiting the frequency of treatments.

By decreasing dialysis treatment option and thus inadvertently increasing the barriers to home dialysis, the LCD proposed changes are also contrary to intent of the Congressional Mandate in the Social Security Act<sup>2</sup>:

(6) It is the intent of the Congress that the ***maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated*** and that the ***maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment***. The Secretary shall consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

## Impact on the Patient

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<sup>1</sup> Pauly RP, Gill JS, Rose CL, Asad RA, Chery A, Pierratos A, Chan CT. Survival among nocturnal home haemodialysis patients compared to kidney transplant recipients. *Nephrol Dial Transplant*. 2009;24:2915-2919. Nishio-Lucar AG, Lyons GR, Subhasish B, Lockridge RS. Intensive Home Hemodialysis Survival Is Comparable to Deceased Donor Kidney Transplant. *ASN Kidney Week 2017*, New Orleans, LA [Abstract FR-PO1017].

<sup>2</sup> SSA Section 1881(c)(1)(A)(i)(6)

Limiting dialysis payment for more than three times per week to only patients with the acute conditions listed in the draft LCD is shortsighted, and poses an ethical dilemma for physicians caring for patients whose conditions benefit from more frequent dialysis. Studies report that patients prescribed more than three treatments per week have been able to achieve improvements in, among other things, left ventricular hypertrophy, hypertension (using fewer medications), hyperphosphatemia, depression, post-treatment recovery time, sleep disturbances, and restless legs syndrome. Not all patients with these conditions always need more frequent dialysis, but it is imperative for physicians to be able to individualize patient care based on a number of factors, including the patient's other chronic conditions.<sup>3</sup>

Further supporting the concept that chronic, more frequent hemodialysis may be needed by individual patients, the KDOQI Clinical Practice Guideline for Hemodialysis instructs physicians on an individual, patient-by-patient basis to “consider additional hemodialysis sessions or longer hemodialysis treatment times for patients with large weight gains, high ultrafiltration rates, poorly controlled blood pressure, difficulty achieving dry weight, or poor metabolic control (such as hyperphosphatemia, metabolic acidosis, and/or hyperkalemia).” There is substantial evidence, including that discussed briefly above, that suggests there are clinical benefits associated with more frequent hemodialysis.<sup>4</sup>

### **Protecting the Physician – Patient Relationship**

HDU feels that the physician-patient relationship is sacrosanct, and the physician must not be constrained by regulation from prescribing the best and most effective treatment for the patient and thus unable to effectively provide high-quality and safe care. Limiting adequate treatment will affect a subpopulation who experience acute problems occurring on a chronic basis (an example of which is fluid overload), and we believe policy such as set forth in the LCD creates a restriction that is counter to the underlying purpose of the ESRD program. We would urge you to seek solutions that allow chronic patients who definitively need extra dialysis treatments within a month to receive them in a covered and compliant manner. If patients are deprived of appropriate and sufficient treatment, they will be forced to seek treatment in the emergency department or to be hospitalized, thus offsetting any potential savings realized from cutting treatments.

Furthermore, Section 1801 [42 U.S.C. 1395] of the Medicare Act of 1965 states that “nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.” HDU feels that by limiting dialysis payment to three times per week, the MACs are essentially prescribing treatment, or at a minimum, overriding the doctor's ability to provide appropriate and safe care.

### **Negative Impact on Care Delivery Quality Measures (MIP, QIP, and DFC)**

One unintended consequence of the LCD is that limiting the number of dialysis sessions for the ESRD patient will also confound the ability of providers to successfully achieve the quality goals set

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<sup>3</sup> [http://www.ajkd.org/issue/S0272-6386\(16\)X0004-2](http://www.ajkd.org/issue/S0272-6386(16)X0004-2)

<sup>4</sup> National Kidney Foundation. KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 update. Am J Kidney Dis. 2015 Nov;66(5):884-930.

forth by CMS, thus negatively affecting clinic ratings due to increased hospitalizations, hypervolemia, and other side effects of insufficient dialysis. Another would be the disincentive to the prescribing of home hemodialysis, which is a federal mandate under the Social Security Act.

## Conclusion

We implore HHS to ask the MAC's to do the right thing for the patient, and respect the doctor- patient relationship. We ask that CMS ensure that all patients who medically require additional dialysis receive these services in a manner that is consistent with the intent of CMS policy. We recognize and respect the need to enact cost-saving measures in the ESRD program, and stand ready to work with CMS to do so – but not at the expense of the patients.

HDU feels certain that if a loved one of yours were on dialysis, you would not want their treatment restricted, handed disability papers, and told to accept that this is their life, going forward. You would want them to live to their fullest potential. This is what HDU wants for all dialyzors. More frequent hemodialysis allows patients to incorporate dialysis into their lives with less disruption. Additionally, a recent study showed that more frequent dialysis had statistically similar long-term outcomes equal to those of deceased donor transplants.<sup>5</sup>

Home Dialyzors United produced a patient video that highlights the clinical benefits of more frequent dialysis, in the dialyzors own words. HDU has shared this with CMS, the MAC's and would like to now share it with you at the following link [Patients Speak Out](http://homedialyzorsunited.org/video-patients-speak). [\*\*http://homedialyzorsunited.org/video-patients-speak\*\*](http://homedialyzorsunited.org/video-patients-speak)

In closing, HDU welcomes the opportunity to work collaboratively with HHS, CMS and the MACs in an effort to improve the quality of care provided to the kidney patients within its jurisdictions. Please direct any questions or comments regarding this correspondence to [Denise Eilers, President](#).

Sincerely,

[Denise Eilers](#)

President,

Home Dialyzors United

563-888-5463

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<sup>5</sup> Nishio-Lucar AG, Lyons GR, Subhasish B, Lockridge RS. Intensive Home Hemodialysis Survival Is Comparable to Deceased Donor Kidney Transplant. ASN Kidney Week 2017, New Orleans, LA [Abstract FR-PO1017].

*INSPIRING, INFORMING, AND ADVOCATING FOR AN EXTRAORDINARY QUALITY OF LIFE FOR THE HOME DIALYSIS COMMUNITY.*